UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION **THIS DOCUMENT RELATES TO: SELF-FUNDED PAYER TRACK**	**Case 2:23-md-03080** **MDL No. 3080** **JUDGE BRIAN R. MARTINOTTI** **JUDGE RUKHSANAH L. SINGH**

BRIEF IN SUPPORT OF THE SELF-FUNDED PAYER PLAINTIFFS' MOTION FOR LEAVE TO AMEND

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INTRODUCTION

Self-Funded Payer Track Plaintiffs respectfully seek leave to amend their complaints to include allegations and claims against the PBM Defendants' affiliated rebate aggregators, Zinc Health Services, LLC ("Zinc") (CVS Caremark), Ascent Health Services, LLC ("Ascent") (Express Scripts), and Emisar Pharma Services, LLC ("Emisar") (OptumRx).[1] These rebate aggregators are key players in the Insulin Pricing Scheme—they obfuscate the payment trail of rebates and unearned "fees," "credits," and "discounts" among the PBMs and Manufacturers and generate new, gratuitous fees, which further inflate the list prices of the at-issue medications. As a former Optum executive has disclosed, "[t]he intention of the [rebate aggregator] is to create a fee structure that can be retained and not passed on to a client." Ex. 3[2], Admin. Compl., Dkt. No. 9437, at ¶ 54, *In the Matter of Caremark Rx, LLC et al.*, (F.T.C. Sept. 20, 2024).

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[1] For the Court's reference, an exemplar proposed amended complaint reflecting Plaintiffs' proposed allegations against the rebate aggregators (using the currently operative complaint filed in *County of Monmouth, N.J. v. Eli Lilly and Company, et al.*, Case No. 2:23-cv-03916 (D.N.J.) [ECF No. 18]) is attached as Exhibit 1 to the Declaration of David R. Buchanan submitted herewith. A redline version indicating in what respects the proposed amended complaint differs from the currently operative complaint is attached as Exhibit 2.

[2] All citations to "Ex. ___" refer to exhibits to the Declaration of David R. Buchanan submitted herewith.

Despite their critical role, little was known about these rebate aggregators, also referred to by the PBMs as "group purchasing organizations," before the United States Federal Trade Commission (the "FTC") filed an administrative complaint against them and the PBMs on September 20, 2024. This was by design: the PBMs went to great lengths to conceal the existence and operations of the rebate aggregators. Although they are closely held affiliates or subsidiaries of the PBMs, details about these rebate aggregators (including their names) are not disclosed in the PBMs' SEC filings; two of the three operate abroad; and little information about their structure, leadership, or purpose has been made publicly available. As a result, until recently, there was little reporting in the media about the rebate aggregators, and the stories that eventually came to light did not disclose critical details about their operations, particularly with regard to the at-issue medications.

The FTC incorporated the rebate aggregators into an investigation of the PBMs in mid-2023, but when it published an interim report of its findings one year later in July 2024 (just prior to the amendment deadline in this case), the report included less than two pages of text on the entities, reporting that the FTC was engaged in "ongoing negotiations" with the PBMs about the production of documents and data on the rebate aggregators, and that "some" had stated that they did not expect to complete production until 2025. *See* Fed. Trade Comm'n Office of Policy Planning, Interim Staff Report, *Pharmacy Benefit Managers: The Powerful*

Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, at 23 (July 9, 2024) (the "Interim Staff Report").[3]

The FTC later filed its administrative complaint against the PBMs and rebate aggregators on September 20, 2024, seven weeks after the Court's deadline to amend or add parties, which, in turn, fell just six weeks after the Court's initial discovery plan. Though redacted, the FTC's complaint revealed for the first time critical details about the aggregators' operations. The complaint also reflected the agency's determination—after its review of documents and data outside the public record—that there was sufficient evidence to pursue plausible claims against the aggregators for their roles in the Insulin Pricing Scheme at the heart of this MDL. Armed with this knowledge, Plaintiffs' counsel carefully reviewed and analyzed the FTC complaint and drafted allegations against Zinc, Ascent, and Emisar. And just weeks later, on November 7, 2024, Plaintiffs' counsel notified Defendants, and then the Court, that the Self-Funded Payer Plaintiffs would seek leave to amend their pending complaints to include these new allegations and pursue the once-concealed damages retained by the rebate aggregators. Those Plaintiffs now move for leave to amend their complaints.[4]

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[3] *Available at* https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[4] The specific Self-Funded Payer Track Plaintiffs to which this Motion applies are identified in Schedule A attached to the Notice of Motion. The applicable Plaintiffs

BACKGROUND

This multidistrict litigation comprises hundreds of individual cases against Manufacturer Defendants Eli Lilly and Company, Sanofi Aventis U.S., LLC, and Novo Nordisk Inc., and the PBM-Defendant conglomerates Plaintiffs commonly refer to as CVS Caremark, Express Scripts, and OptumRx. The Self-Funded Payer Plaintiffs—all organizations and entities that operate self-funded health insurance plans for their employees—allege that Defendants orchestrated a scheme to artificially inflate the list prices of insulin, insulin-analog, and GLP-1 diabetes medications, and extract exorbitant profits from payers by, among other things, retaining rebates and unearned "fees," "discounts," and other "credits" that rightfully belonged to payors. *See, e.g.*, Second Am. Compl., *County of Albany, N.Y. v. Eli Lilly & Co., et al.* [ECF No. 158].

On April 24, 2024, certain Self-Funded Payer Track Plaintiffs (selected by Defendants) filed amended complaints that would be subject to Defendants' motions to dismiss. [ECF Nos. 158, 159, 160].[5] Less than six weeks later, on June 7, 2024,

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are those who filed actions prior to the August 1, 2024 deadline for amending complaints. *See* Case Mgmt. Order #10 [ECF No. 198]. Self-Funded Payer Track Plaintiffs who filed actions after this deadline may amend their complaints as of right under Rule 15(a)(1)(B) until "21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier."

[5] *See* Case Mgmt. Order #6 (Stipulation and Order Governing Motions to Dismiss in the Self-Funded Payer Track) [ECF No. 128].

the Court issued Case Management Order #10, which set forth its initial discovery plan, established a discovery schedule, directed parties to continue to meet and confer on Master Discovery Requests and Plaintiff Fact Sheets, and, among other things, set the deadline to "amend or add parties" for August 1, 2024, less than two months after the Court's implementation of the initial discovery plan. *See* Case Mgmt. Order #10 [ECF No. 198] at 2-3.[6]

One month after the Court issued its initial discovery plan, on July 9, 2024, the FTC issued its Interim Staff Report on the progress of its investigation into the PBMs' roles in inflating the prices of prescription drugs. *See* Interim Staff Report at 21-23. The FTC had launched the investigation in June 2022 and eventually expanded it to include group purchasing organizations, or GPOs controlled by the PBMs known as "rebate aggregators," which the PBMs had established between 2018 and 2022 to negotiate and collect rebates and other fees for the PBMs and other clients. *See* Ex. 1, Proposed Am. Compl. at ¶¶ 16(c), 19, 107(c), 463-72, 484-84, 563. Specifically, CVS Caremark controls Zinc; Express Scripts controls Ascent; and OptumRx controls Emisar. *See id.* ¶¶ 102-05, 149-51, 190-92[7]; Ex. 3, Admin.

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[6] Party discovery was not formally opened until four months later, upon entry of Case Management Order #13 [ECF No. 313] on October 15, 2024.

[7] The FTC issued compulsory orders to Zinc and Ascent in May 2023, and to Emisar in June 2024. *See* U.S. Fed. Trade Comm'n, *FTC Deepens Inquiry into* Prescription Drug Middlemen, May 17, 2023, *available at* https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-

Compl., *In the Matter of Caremark Rx, LLC et al.*, Dkt. No. 9437 (F.T.C. Sept. 20, 2024) at ¶¶ 17, 22, 27.

The Interim Staff Report dedicated less than two pages of text to the rebate aggregators' role in inflating prescription drug prices. *See* Interim Staff Report at 21-24. It characterized the rebate aggregators as PBM affiliates that "negotiate contracts, including rebates, with drug manufacturers—a task that PBMs historically engaged in directly." *Id.* at 21. The report then explained why the aggregators were formed and speculated that the PBMs "*may* have spun off the[] rebate aggregators as separate entities" for illegitimate purposes, "such as to retain revenue from incremental fee structures." *Id.* at 22 (emphasis added). The report also observed that "[i]nternal PBM documents *appear* to show novel methods of fee generation from these new rebate aggregators," without offering any insight into the methods referenced. *See id.* (same). Finally, the Interim Staff Report noted:

> In May and June 2023, the Commission issued supplemental 6(b) Orders to the Big 3 PBMs' rebate aggregators to learn more about their operations and obtain data and documents. FTC staff has engaged in ongoing negotiations with these entities regarding their required productions of documents and data, with some stating that they currently do not anticipate completing productions until 2025.

Id. at 23.

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middlemen; U.S. Fed. Trade Comm'n, *FTC Further Expands Inquiry into Prescription Drug Middlemen Industry Practices*, June 8, 2023, *available at* https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

The FTC finally filed an administrative complaint against the PBMs and their rebate aggregators on September 20, 2024, and released a public version of the complaint with significant redactions. *See* Ex. 3. The administrative complaint included new allegations describing the rebate aggregators' role in the Insulin Pricing Scheme and reflected the FTC's judgment that the documents produced during its two-year investigation supported colorable claims against Zinc, Ascent, and Emisar. *See id.* And whereas the earlier Interim Staff Report "principally focuse[d] on the impact of these changing [PBM-related] market dynamics on the operation and vitality of the nation's pharmacies" (Interim Staff Report at 71), the FTC's administrative complaint was narrowly targeted at the rebate aggregators' "anticompetitive and unfair rebating practices *that have artificially inflated the list price of insulin drugs*."[8]

Plaintiffs' counsel reviewed and analyzed the FTC complaint and drafted proposed allegations to incorporate into their already pending complaints. Plaintiffs' counsel also included these allegations in most, if not all, Self-Funded Payer Track complaints moving forward. *See, e.g.*, Compl. [ECF No. 1] ¶¶ 16(c), 24, 103-06,

[8] U.S. Fed. Trade Comm'n, *FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices*, Sept. 20, 2024, *available at* http://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices. (emphasis added).

149-52, 191-93, 472-85, *N.J. Mun. Emps. Benefit Fund v. Eli Lilly & Co., et al.*, No. 2:25-cv-351 (D.N.J.).

On November 7, 2024, Plaintiffs' counsel informed Defendants, and then the Court, of their intention to seek leave to amend the Self-Funded Payer complaints that do not include allegations and claims against Zinc, Ascent, and Emisar. Plaintiffs now move for leave to amend these pending complaints.

LEGAL STANDARD

"The court should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). "This liberal amendment philosophy limits the district court's discretion to deny leave to amend." *Goldberg v. United States*, No. 17-cv-6024, 2021 WL 3550071, at *2 (D.N.J. Aug. 11, 2021) (quoting *Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984)). To be sure, "a court should allow a party to amend its pleading so long as there is no undue delay, bad faith, dilatory motive, undue prejudice or futility of the amendment[.]" *Heffley v. Fed. Bur. of Prisons FCI Fort Dix*, No. 17-cv-3647, 2022 WL 1541478, at *1 (D.N.J. May 16, 2022) (citing *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000)). "This liberal amendment regime helps effectuate the general policy embodied in the Federal Rules favoring resolution of cases on their merits." *Mullin v. Balicki*, 875 F.3d 140, 149 (3d Cir. 2017).

Where a motion for leave to amend is filed after a scheduling-order deadline has passed, then the party seeking leave to amend must also demonstrate good cause

under Rule 16(b)(4) of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 16(b)(4); *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 84 (3d Cir. 2010). To establish good cause, the movant must show due diligence. *Race Tires Am., Inc.*, 614 F.3d at 84. "Due diligence can be met if the 'delay in filing the motion to amend stemmed from any . . . factor which might understandably account for failure of counsel to undertake to comply with the Scheduling Order,'" including even mistake or excusable neglect. *Curtis v. Callahan*, No. 19-cv-21164, 2024 WL 1929503, at *3 (D.N.J. May 1, 2024) (quoting *Young v. United States*, 152 F. Supp. 3d 337, 353 (D.N.J. 2015)). What will constitute "good cause" to warrant modification of a scheduling order under Rule 16(b)(4) lies within the Court's discretion and "necessarily varies with the circumstances of each case." *Bright v. Tyson*, No. 15-cv-8038, 2019 WL 2619247, at *3 (D.N.J. June 25, 2019). Once the movant establishes good cause under Rule 16, then the Court may evaluate the proposed pleading under Rule 15. *Harbor Laundry Sales, Inc. v. Mayflower Textile Serv. Co.*, No. 09-cv-6259, 2011 WL 6303258, at *3 (D.N.J. Dec. 16, 2011).

ARGUMENT

I. GOOD CAUSE EXSITS FOR THE PROPOSED AMENDMENTS UNDER RULE 16(b)(4).

Plaintiffs have established good cause to allow their proposed amendment under Rule 16(b)(4) because, despite their diligence, the facts supporting their proposed allegations and claims against the rebate aggregators did not come to light

until weeks *after* the August 1, 2024 deadline for amended pleadings—when the FTC's administrative complaint tied the rebate aggregators to the Insulin Pricing Scheme. Plaintiffs notified Defendants and the Court of their intention to amend promptly after the release of the FTC complaint, as soon as they had reviewed the FTC's administrative complaint asserting claims against Zinc, Ascent, and Emisar and drafted proposed allegations against those entities.

The FTC's complaint was unlike any public reporting on the rebate aggregators that came before it; it was based on an investigation that had yielded "millions of documents and several terabytes of data"[9] from the PBMs and rebate aggregators and was the first public report detailing the rebate aggregators' roles in the Insulin Pricing Scheme or any specifics describing their operations. Beyond that, the mere decision to file the complaint told Plaintiffs' counsel that the record produced to the FTC included sufficient data and detail to support plausible claims against the rebate aggregators.

The FTC complaint also revealed—for the first time—key facts about the aggregators' operations; for example, the complaint disclosed that the PBMs' rebate-aggregator affiliates:

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[9] Letter from FTC Chair Lina M. Khan to Sen. Marsha Blackburn, Feb. 13, 2024, at 3, *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/notice-penalty-offenses_4.13.2023_foia_2023-00928.pdf.

- essentially perform the same commercial rebate contracting function that the PBMs once handled themselves and described those specific functions (Ex. 3 ¶¶ 42, 43, 45, 47, 49, 232);

- are staffed by personnel who previously held the same functional roles at the PBM Defendants (*id.* ¶ 42);

- make their rebate contracts with the Manufacturers available for payers' review only on-site at the aggregators' physical office (*id.* ¶ 54);

- attribute administrative fees to maintaining and overseeing the rebate program, negotiating and contracting with clients to participate in the rebate program, monitoring compliance with rebate eligibility requirements, and calculating and invoicing the rebates applicable to eligible drug utilization (*id.* ¶ 45); and

- extract data fees from the Manufacturers as part of their commercial rebate negotiations, which grants the Manufacturers access to a portal that contains utilization and other data for the manufacturer's drugs (*id.* ¶¶ 47, 48, 165).

Though redacted, the FTC complaint also provides details about the data fees collected by rebate aggregators and focuses on insulin and insulin-analogs (*id.* ¶¶ 47, 48, 165-70, 208, 226, 243), while prior reports discussing the rebate aggregators were broader in scope.

Indeed, information about the rebate aggregators available before the FTC complaint's filing was limited at best. The Senate Finance Committee's January 2021 report on rising insulin costs mentioned rebate aggregators only in passing, referenced only Express Scripts' GPO, Ascent, and concluded without describing

Ascent's operations that "[n]ew arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress."[10]

The Ohio Attorney General sued Express Scripts, Inc., Cigna Group, Evernorth Health, Inc., and Ascent in March 2023, but its complaint sounded in antitrust and described Ascent's role in inflating insulin prices in only the most general terms. The Ohio complaint, unlike those at issue here, focused on the defendants' conduct as it affected retail pharmacies and un- and underinsured patients, and centered on allegations—asserted on information and belief—that Ascent, by virtue of its dual ownership and client base, served as a vehicle for pharmacy benefit managers to "aggregate and access each other's pricing, discount, rebate, and negotiations information." Compl. [ECF. No. 1-3] ¶¶ 27-29, 45, 174-91, *State of Ohio, ex rel. Yost v. Ascent Health Servs., et al.*, 2:23-cv-1450 (S.D. Ohio). The Ohio complaint also included no allegations about Zinc or Emisar. *See id.*

The FTC issued compulsory orders to the rebate aggregators in May and June 2023 but did not disclose any information arising from those orders until it issued the Interim Staff Report on July 9, 2024. Even then, the Interim Staff Report was "principally focuse[d]" on the PBMs' deleterious effect on the "operation and

[10] U.S. Sen. Fin. Comm., *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, Jan. 14, 2021, *available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

vitality of the nation's pharmacies." Interim Staff Report at 71. In fact, the FTC dedicated less than two pages of text to the PBMs' rebate aggregators and described their role in inflating list prices only in the most general terms. *Id.* at 21-23. The Interim Staff Report explains that rebate aggregators negotiate contracts, including rebates, for the PBMs, but only speculates that the PBMS "*may* have spun off these rebate aggregators as separate entities for other purposes, such as to retain revenue from incremental fee structures." *Id.* at 22 (emphasis added). The report similarly notes that documents produced by the PBMs "*appear* to show novel methods of fee generation" but fails to provide any detail about the types of fees collected by the GPOs. *Id.* at n.96 (citing documents but redacting details about their contents). Moreover, raising additional doubt as to the completeness and reliability of the interim report, the report discloses that none of the "Big 3" rebate aggregators had completed the required production of documents and data, and some did not anticipate completing production until 2025. *Id.* at 23.

And although media outlets published reports in the months preceding the FTC complaint's release describing the rebate aggregators' involvement in prescription drug pricing, Plaintiffs' counsel knew when these reports were published that the FTC was investigating the rebate aggregators and that a comprehensive report was pending. And, unsurprisingly, none of these outlets'

reports offered the detail or the specific focus on insulins that was provided by the FTC complaint in September 2024.

Here, the grounds for Plaintiffs' proposed amendment first arose *after* the deadline for amending complaints when the FTC filed its complaint implicating the rebate aggregators in the Insulin Pricing Scheme. Plaintiffs initiated the process for amendment just weeks later. As such, there exists good cause to allow Plaintiffs to amend their complaints to incorporate these newly unearthed facts. *See Ramos v. Walmart Inc.*, No. 21-cv-13827, 2024 WL 4318603, at *4 (D.N.J. Sept. 24, 2024) ("'Good cause' under Rule 16(b) enquires into the moving party's diligence in litigating the case based on best available information at the relevant juncture."). The foregoing factors adequately account for Plaintiffs' inability to seek leave to amend prior to the scheduling-order deadline, such that a finding of "good cause" is warranted. *See Curtis*, 2024 WL 1929503, at *4 (finding "good cause" when movant "established that there were sufficient factors to "understandably account" for failure to amend complaint in accordance with scheduling order).

II. THE COURT SHOULD GRANT LEAVE TO AMEND UNDER RULE 15(a)(2).

As set forth above, a court should freely allow amendment "so long as there is no undue delay, bad faith, dilatory motive, undue prejudice or futility of the amendment[.]" *Heffley*, 2022 WL 1541478, at *1. The Court should allow the filing of the proposed amendments here because there was no undue delay on the part of

Plaintiffs, amendment will not unduly prejudice Defendants or the rebate aggregators, and amendment would not be futile. Moreover, considerations of judicial efficiency strongly support Plaintiffs' proposed amendment.

A. There Is No Undue Delay.

For the same reasons that establish Plaintiffs' diligence, there has been no undue delay by Plaintiffs in seeking leave to amend to add allegations and claims against the PBMs' rebate aggregators. *See Korrow v. Aaron's, Inc.*, 300 F.R.D. 215, 223–24 (D.N.J. 2014) (considering "good cause" and "undue delay" analysis together); *see also Blue Gentian, LLC v. Tristar Prods., Inc.*, No. 13-cv-1758, 2024 WL 4719560, at *7 (D.N.J. Nov. 8, 2024) ("Much of the analysis for undue delay under Rule 15 naturally overlaps with the good-cause analysis under Rule 16.").

Additionally, "[d]elay alone does not constitute grounds for denying leave to amend, and delay only becomes 'undue' when it places an unwarranted burden on the court or when the plaintiff has had previous opportunities to amend." *Crincoli v. Geico Ins. Co.*, No. 20-cv-3380, 2020 WL 7264145, at *2 (D.N.J. Dec. 10, 2020) (citing *Bjorgung v. Whitetail Resort, LP*, 550 F.3d 263, 266 (3d Cir. 2008)). Plaintiffs have not had previous opportunities to amend specific to the allegations at issue and, as explained above, could not have brought claims against the aggregators in good faith before they reviewed the FTC complaint.

Nor will allowing the proposed amendments place an unwarranted burden on the Court. The rebate-aggregator defendants—Zinc, Ascent, and Emisar—are members of the PBM conglomerates that are already party to this litigation—CVS Caremark, Express Scripts, and OptumRx, respectively.[11] And the allegations against the rebate aggregators align with the allegations against their corporate parents. *See* Ex. 1 ¶¶ 16(c), 19, 463-72, 463-72, 484-84, 563. As explained in the FTC complaint, the rebate aggregators assumed functions once performed by the PBMs, and already at issue in this litigation. *See* pp. 10-11, *supra.* Finally, since the FTC published its administrative complaint, new cases have been filed directly in this MDL asserting allegations and claims against the rebate aggregators. *See, e.g.*, *N.J. Mun. Emps. Benefit Fund*, pp. 7-8, *supra*. The rebate aggregators are already defendants in this MDL, and their misconduct is already at issue. Allowing these Plaintiffs to amend their complaints will impose no additional burden on the Court.

B. Defendants Will Not Be Prejudiced by Amendment.

Defendants will not be prejudiced by the proposed amendments. As explained above, the misconduct described in Plaintiffs' new allegations is consistent with the misconduct attributed to the PBMs in Plaintiffs' currently operative complaints.

[11] To be sure, in new cases filed directly in this MDL in December and January, which include allegations and claims against the rebate aggregators, each PBM Defendant's counsel has accepted service for its affiliated rebate aggregator. *See, e.g.*, Waivers of Service [ECF Nos. 4, 5 11], *Braman Motors, Inc., et al. v. Eli Lilly & Co., et al.*, No. 2:24-cv-11531 (D.N.J.).

And, as explained in the FTC complaint, the rebate aggregators assumed functions once performed by the PBM Defendants. *See, e.g.*, Ex. 3 ¶¶ 42, 43, 45, 37, 49. They negotiate contracts, including rebates, with the Manufacturers, and collect rebates and fees on the PBMs' and their own behalf. *See id.* These rebates and fees drive up the costs of the at-issue medications, and their obfuscation, which the rebate aggregators enable, allows the PBMs and rebate aggregators to retain a percentage of the medications' inflated list prices. *See id.* ¶¶ 42-54. The new allegations against the rebate aggregators provide crucial detail about the flow of funds among the PBMs, the Manufacturers, and payers, and capture damages that the PBMs have attempted to hide through these aggregators in the form of various unearned fees.

In fact, Plaintiffs included general allegations about the rebate aggregators in their original complaints. *See, e.g.*, Second Am. Compl., *County of Albany, N.Y. v. Eli Lilly & Co., et al.*, ¶¶ 23, 432, 460-68 [ECF No. 158]. These allegations described the PBMs' efforts to obfuscate the payment trail for rebates and retain profits owed to payers but lacked the detail necessary to support fully developed claims against the aggregators. *See id.* Defendants cannot claim to be surprised by these new allegations; and the only "prejudice" they may endure is the eventual surrender of funds that rightfully belong to payers.

C. The Proposed Amendments Are Not Futile.

An amendment is only futile "if the amended complaint would not survive a motion to dismiss for failure to state a claim upon which relief could be granted." *Colonial Sur. Co. v. Alpha Software Corp.*, No. 2:17-cv-01701, 2019 WL 2137365, at *3 (D.N.J. May 16, 2019). "Thus, in determining futility the same legal standard employed under a Rule 12(b)(6) motion to dismiss is applied." *Id.* However, "[g]iven the liberal standard for the amendment of pleadings, 'courts place a heavy burden on opponents who wish to declare a proposed amendment futile.'" *High 5 Games, LLC v. Marks*, No. 13-cv-716, 2018 WL 2134038, at *4 (D.N.J. May 9, 2018) (quoting *Pharm. Sales & Consulting Corp. v. J.W.S. Delavau Co.*, 106 F. Supp. 2d 761, 764 (D.N.J. 2000)). And the evaluation of futility under Rule 15 does not contemplate substantive motion practice on the merits of the claims:

> If a proposed amendment is not clearly futile, then denial of leave to amend is improper. This does not require the parties to engage in the equivalent of substantive motion practice upon the proposed new claim or defense; this does require, however, that the newly asserted defense appear to be sufficiently well-grounded in fact or law that it is not a frivolous pursuit.

Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 468-69 (D.N.J. 1990). "Effectively, this means that the proposed amendment must be frivolous or advance a claim or defense that is legally insufficient on its face." *High 5 Games*, 2018 WL 2134038, at *4.

Here, the FTC's decision to file an administrative complaint against Zinc, Ascent, and Emisar establishes that Plaintiffs' proposed amendments are not futile. The FTC filed its complaint after initiating an investigation that produced "millions of documents and several terabytes of data," *see* p. 10, *supra*, and determining that the evidence supported plausible claims against the "Big Three" rebate aggregators. Plaintiffs have based their proposed allegations on the FTC's well-researched allegations. *See, e.g.*, Ex. 1 ¶¶ 463-72, 484-84; *see generally* Ex. 3. Plaintiffs expect that full discovery will uncover additional detail about the rebate aggregators' involvement in the Insulin Pricing Scheme and establish, as a former Optum executive has conceded, that the intention and function "of the [rebate-aggregator] G.P.O. is to create a fee structure that can be retained and not passed on to a client." Ex. 3 ¶ 54. Allowing the aggregators to retain these fees would only reward their clear misconduct. The Court should allow Plaintiffs to pursue the damages retained by Zinc, Ascent, and Emisar.

D. Amendment Will Promote Judicial Economy and Effective Case Management.

Finally, "[j]udicial efficiency and effective case management are matters that can be considered in deciding whether amendment should be allowed." *High 5 Games*, 2018 WL 2134038, at *5. *See also Mullin*, 875 F.3d at 157 ("Judicial economy is an equitable consideration that can be considered in deciding whether amendment should be allowed.").

As set forth above, since the filing of the FTC's complaint, many new cases have been filed directly in this MDL asserting claims against the rebate aggregators. *See, e.g.*, *N.J. Mun. Emps. Benefit Fund*, pp. 7-8, *supra*. Because the rebate aggregators are already named defendants in this MDL, "it makes sense for the parties and the Court to allow these parties to litigate all their issues in one place and with one judge"—rather than constrain these Plaintiffs to institute separate proceedings against the aggregators. *See High 5 Games*, 2018 WL 2134038, at *5 (finding amendment promoted judicial efficiency because if denied, plaintiff "could simply file a new case with the same contentiousness, the same discovery problems, the same costs – just under a new docket number.").

CONCLUSION

The Court should grant Plaintiffs' motion for leave to amend their complaints to include allegations and claims against Zinc, Ascent, and Emisar.

Respectfully submitted,

Dated: January 31, 2025

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